REMARKS

In the aforesaid Office Action, claims 11-18 were rejected under 35 USC §112, second paragraph, claims 11, 13-19, 21-26, and 39-66 were rejected under 35 USC §102(b) as being anticipated by Evard (U.S. Patent No. 5,242,396), claims 11, 13, 16-18, 39, 42-45, 48-51 and 54-56 were rejected under 35 USC §102(b) as being anticipated by Shank et al. (U.S. Patent No. 5,147,317), claim 12 was rejected under 35 USC §102(b) as being anticipated by Hibbs et al. (U.S. Patent No. 4,950,257), and claims 12 and 20 were rejected under 35 USC §103(a) as being unpatentable over Evard in view of Maguire et al. (U.S. Patent No. 6, 599,288). Claims 11-26, 51, 53, 56-60, 65 and 66 are pending.

The Examiner rejected claims 11-18 under 35 USC §112, second paragraph, stating that the body of claim 11 does not positively claim a catheter. Applicants have amended claim 11 to obviate the rejection.

The Examiner rejected claims 11, 13-19, 21-26, and 39-66 under 35 USC §102(b) as being anticipated by Evard, stating that Evard discloses a mandrel comprised of a variable stiffness non-metal material. However, Evard does not disclose or suggest a non-metal mandrel having a proximal section with a first crystallinity and a distal section with a second crystallinity lower than the first crystallinity such that the proximal section is stiffer than the distal section. Instead, Evard discloses changing the outer diameter of the mandrel to provide flexibility in the catheter distal portion. Thus, Evard does not teach every element of the claims (e.g., the proximal section of the mandrel having a

higher crystallinity than the distal section) as required for a rejection under 35 USC §102(b).

Regarding claim 14, the Examiner states that the distal section of the mandrel extends past the proximal portion of the inflatable member (i.e., proximal portion of 23). However, the mandrel does not extend to a location along the length of the catheter located in the inflatable interior of the inflatable member. Instead, Evard specifically discloses that the mandrel "extends from the proximal end of the catheter shaft into the distal portion of the catheter shaft but it terminates short of the proximal end of the inflatable member, e.g., at least 5 mm. from the proximal end of the inflatable member, i.e., the proximal end of the proximal taper of the inflatable member" (emphasis added). Thus, although the Evard mandrel does extend to a location along the waist portion 23 of the inflatable member, the waist portion 23 does not define the inflatable interior of the inflatable member, and is instead proximal to the inflatable interior of the inflatable member. Moreover, regarding claim 16, Evard does not disclose or suggest that the mandrel extends to the distal end of the inflatable interior of the inflatable member.

The Examiner rejected claims 11, 13, 16-18, 39, 42-45, 48-51 and 54-56 under 35 USC §102(b) as being anticipated by Shank et al., stating that Shank et al. discloses mandrel 10 comprised of a variable stiffness, non-metal material (see column 7, line 5). However, Shank et al. does not disclose or suggest a solid-walled mandrel comprised of a non-metal material as required by claim 11 or a non-metal material mandrel formed of a polyetheretherketone polymeric material as in claim 51. Instead, in Shank et al. the body of the mandrel (i.e., guidewire corewire 10) is metallic. Although Shank et al. does

disclose providing a polymeric Teflon coating on the metallic body, that coating (which the Examiner indicates as corresponding to Applicant's non-metal material mandrel) does not form the mandrel's solid walled body, and similarly is not a non-metal material mandrel formed of a polyetheretherketone polymeric material (as in claim 51).

The Examiner rejected claim 12 under 35 USC §102(b) as being anticipated by Hibbs et al., stating that Hibbs et al. discloses a mandrel 20 comprised of a variable stiffness, non-metal material, and the material is nylon. However, Applicants have carefully reviewed Hibbs et al. and can find no teaching or suggestion of a non-metal mandrel disposed in a catheter shaft lumen as required by claim 12. Instead, the element 20 referred to by the Examiner as being the mandrel, is the introducer itself formed of tubular body portion 24 and tubular tip portion 26, and the tubular members 24, 26 forming said introducer shaft have a catheter disposed therein, and thus are not disposed in a catheter shaft. Therefore, Hibbs does not disclose or suggest a non-metal material mandrel disposed in a catheter shaft.

The Examiner rejected claims 12 and 20 under 35 USC §103(a) as being unpatentable over Evard in view of Maguire et al, stating that Evard discloses the invention substantially as claimed and Maguire et al. discloses a catheter polyimide mandrel. However, as discussed above, Evard does not disclose or suggest a non-metal mandrel having a proximal section with a first crystallinity and a distal section with a second crystallinity lower than the first crystallinity such that the proximal section is stiffer than the distal section.

Applicants wish to note that the Examiner has indicated that added claims 57, 61, 63 and 65 have not been entered and alternatively, elsewhere has indicated that they have been entered. Clarification is hereby requested.

Applicants wish to bring to the attention of the Patent Office the reference listed on the attached PTO/SB/08B and request that it be considered by the Examiner. This Information Disclosure Statement is being submitted pursuant to 37 CFR 1.97(c)2 and therefore a fee is due.

In light of the above amendments and remarks, applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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